Sticky Wires * A novel technique for temporary epicardial pacing wire placement.

Published: 26-01-2009
Last updated: 06-05-2024

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON33566

Source
ToetsingOnline

Brief title
Sticky Wires

Condition

- Cardiac arrhythmias

Synonym
Several diseases can be treated with temporary epicardial pacing: brady- or tachyarrhythmia's.

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Temporary epicardial pacing

Outcome measures

Primary outcome

1. feasibility and ease of novel implant technique (feasibility assessment based on "failure rate" (i.e., lead dislodgement)); 2. acute and chronic safety of implant technique; 3. electrical performance of the new leads; 4. force needed to extract the lead out of pace patch; 5. complications upon withdrawal of the lead.

Secondary outcome

NA

Study description

Background summary

Temporary epicardial leads are often placed after cardiac surgery for treatment of arrhythmia*s. Usually, these leads are implanted for several days up to a week in the postoperative course. Epicardial leads are usually placed by stabbing through the myocardium. Pacing leads may contain a coil at the electrode end to secure the lead and prevent accidental dislodgement out of the myocardium. Although used commonly, temporary pacing leads are associated with complications. At implant, bleeding may occur due to the needle stabbing or the presence of a coil at the electrode tip. This, in turn, may require additional sutures to stop bleeding. In addition, extraction of the lead in the postoperative course may cause disruption of coronary anastomoses, atrial and ventricular lacerations, resulting in hemorrhage and cardiac tamponade. Other complications include arrhythmia*s or migration of retained wire.

Study objective

Primarily, this study aims to investigate (i) the feasibility and safety of a novel temporary epicardial pacing wire placement using two unipolar pacing electrodes embedded in a gelatin sponge and (ii) the stability of electrical

performance of the pace patch, both in comparison to conventional leads. Complications upon lead extraction (bleeding) serves as a secondary objective.

Study design

Interventional study without control group.

Intervention

Novel temporary pacing lead is placed with conventional back-up lead.

Study burden and risks

Patients with need for postoperative pacing may be the first ones to benefit from this innovation in the future. The technique may enable easier and less invasive lead placement and extraction, which may lead to less (bleeding) complications. Patients receive standard treatment. The patch in which the lead is embedded is biodegradable and already used in the field of cardiac surgery (used for hemostasis). We investigated in animal studies that novel lead placement does not carry surplus risk over conventional treatment. For safety reasons, a conventional back-up lead is placed. Hereby, we guarantee that patients can be paced under all circumstances, when necessary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All will-competent patients of either sex and above the age of 18 undergoing open chest surgery for the first time in their life for coronary artery bypass grafting (CABG) and/or heart valve surgery are potential candidates for this study.

Exclusion criteria

Exclusion criteria include will-incompetency, age below 18, and prior cardiac surgery.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	26-01-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL25905.068.08